

**REMARKS**

Entry of the foregoing, further and favorable consideration of the foregoing claim amendments, pursuant to and consistent with 37 C.F.R. § 1.115, are respectfully requested.

**Interview**

The undersigned would first like to thank Examiner Hill and Interference Practice Specialists Helms and Wang for the courtesy of granting Applicants an interview on February 9, 2006. During the interview, the content of the present Amendment and Request for Interference was discussed.

**Status**

The instant application was filed on July 15, 2003, with Claims 1-38. See Appendix J, Pages 244-254. In the Preliminary Amendment, also filed on July 15, 2003, Applicants amended Claims 1, 3, 6, and 7; canceled Claims 2, 4-5, and 8-38; and added Claims 39-53. See Appendix Q, Pages 3-11. By the instant Second Preliminary Amendment, Applicants have canceled Claims 1, 3, 6, 7, 39-44, and 46-53, and have added new Claims 54-56. Accordingly, following entry of the foregoing claim amendments, Claims 54-56 will be pending.

**Summary of Claim Amendments**

By the foregoing claim amendments, Applicants have added three new claims, Claims 54-56. Support for Claim 54 may be found throughout the Specification, and at least at Page 1, Lines 15-22; Page 28, Line 22 to Page 29, Line 10; Page 32, Lines 4-25; Page 36, Lines 8-14; Page 60, Lines 4-23; Page 61, Lines

6-11; and Page 68, Lines 3-16. See *Appendix A*; see also *Appendix J*. Support for Claim 55 may be found throughout the Specification, and at least at Page 1, Lines 15-22; Page 28, Line 22 to Page 29, Line 10; Page 32, Lines 4-25; Page 36, Lines 8-14; Page 60, Lines 4-23; Page 61, Lines 6-11; Page 68, Lines 3-16; and Page 248, Original Claim 15. See *Appendix A*; see also *Appendix J*. Support for Claim 56 may be found throughout the Specification, and at least at Page 1, Lines 15-22; Page 28, Line 22 to Page 29, Line 10; Page 32, Lines 4-25; Page 36, Lines 8-14; Page 60, Lines 4-23; Page 61, Lines 6-11; and Page 68, Lines 3-16. See *Appendix A*; see also *Appendix J*. Accordingly, no new matter has been added by the foregoing claim amendments.

The claims added by the instant amendment, Claims 54-56, are claims whose content has been present in Applicants' applications for some time. Specifically, Claims 54 and 55 each result from a combination of what had been Claim 5 of the '625 Application (part of the thirty original claims filed with the application on October 5, 1993) and Claim 47 of the '625 Application (added by an amendment filed August 21, 1995). See *Appendices C and D*. Claim 56 results from what had been Claim 34 of the '531 Application and what had been Claim 5 of the '531 Application (part of the thirty original claims filed with the divisional application on May 13, 1997). See *Appendix E*.

To comply with 35 U.S.C. § 135(b)(1), one may rely on limitations in more than one claim. See, e.g., *Corbett v. Chisholm*, 568 F.2d 759, 765, 196 U.S.P.Q. 337, 343 (C.C.P.A. 1977); see also *Thompson v. Hamilton*, 152 F.2d 994, 996-97, 68 U.S.P.Q. 161, 163-64 (C.C.P.A. 1946). As discussed below, Applicants had on file, prior to August 29, 2001, claims which, as a group, sought to secure a property right

in subject matter substantially the same as that defined by Claim 12<sup>1</sup> of the '468 Patent.

**I. 37 C.F.R. § 41.202(a)(1) – Identification of Interfering Patent**

The unexpired patent that claims subject matter that interferes with the present application is U.S. Patent No. 6,110,468 to Collins *et al.*, "Vaccine for Swine Infertility and Respiratory Syndrome and Method of Use Thereof," issued on August 29, 2000. A copy of the '468 Patent is attached at Appendix F. The Regents of the University of Minnesota, South Dakota State University, and Boehringer Ingelheim Vetmedica, Inc. (pursuant to a Certificate of Correction dated August 13, 2002) are the assignees named on the face of the '468 patent.

The '468 Patent issued from U.S. Patent Application Serial No. 08/927,786 ("the '786 application"), filed September 11, 1997. See Appendix K. The '786 application was a continuation of U.S. Patent Application Serial No. 08/316,529 ("the '529 application"), filed September 30, 1994, now U.S. Patent No. 5,846,805 ("the '805 patent"), issued December 8, 1998; which is a divisional of U.S. Patent Application Serial No. 08/301,738 ("the '738 application"), filed September 6, 1994; which is a continuation of U.S. Patent Application Serial No. 07/860,444 ("the '444 application"), filed March 30, 1992; which is a continuation-in-part of: (1) U.S. Patent Application Serial No. 07/749,839 ("the '839 application"), filed August 26, 1991, now abandoned, and (2) U.S. Patent Application Serial No. 07/760,713 ("the '713 application"), filed September 16, 1991, now abandoned. *Id.*

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<sup>1</sup> Applicants maintain that 35 U.S.C. § 135(b)(1) is similarly satisfied for Claim 3 of the '468 Patent.

The '529 application, now issued as the '805 patent, is entitled, "Culture of Swine Infertility and Respiratory Syndrome Virus in Simian Cells." Boehringer Ingelheim Vetmedica, Inc., South Dakota State University, and the Regents of University of Minnesota (pursuant to a Certificate of Correction dated July 13, 1999) are the assignees named on the face of the '805 patent.

Each of the '738 application, '444 application, and '713 application is entitled, "Vaccine for Mystery Swine Disease and Method for Diagnosis Thereof."

The '839 application is entitled, "Viral Agent Associated with Mystery Swine Disease."

**II(a). Proposed Counts**

For the Examiner's convenience, Applicants offer a Proposed Count with three alternatives. Applicants believe the first alternative of the Proposed Count best defines the interfering subject matter between the parties, but submit that any of the three alternatives interferes under the two-way test (*Winter v. Fujita*, 53 U.S.P.Q.2d 1234, 1243 (Bd. Pat. App. & Int. 1999)) with at least one claim of the '468 patent.

**A. Proposed Count: First Alternative**

Attached Appendix B sets forth a Proposed Count for the Examiner's consideration. The first alternative of the Proposed Count is an alternative Count, prepared after consideration of the subject matter claimed by the respective parties:

Proposed Count: First Alternative	
Claim 55 of the present application	A vaccine which raises an effective immunological response in a pig against exposure to a virus which causes a porcine reproductive and respiratory disease; wherein said vaccine is prepared from a virus cultured in a cell line selected from the group consisting of PSP-36, PSP-36-SAH, and MA-104; wherein said vaccine comprises an effective amount of a biologically-pure virus selected from the group consisting of ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), and ISU-1894, or a virus exhibiting the identifying characteristics of a virus in said group; wherein said virus is attenuated and is prepared by serial passage in cell culture, and a physiologically-acceptable carrier.
OR	OR
Claim 12 of the '468 patent	A vaccine suitable for use in prevention of swine infertility and respiratory syndrome, comprising: (a) attenuated swine infertility and respiratory syndrome virus; and (b) pharmaceutical carrier; wherein the attenuated swine infertility and respiratory syndrome virus produced by a process comprising passaging swine infertility and respiratory syndrome virus ATCC VR-2332 through simian cells to form modified swine infertility and respiratory syndrome virus which is non-zoopathogenic in swine; and wherein said simian cells are MA-104 simian kidney cells.

The interfering subject matter between the '779 Application and the '468 Patent relates to vaccines that protect pigs from Swine Infertility and Respiratory Syndrome ("SIRS"), also known as Porcine Reproductive and Respiratory Syndrome ("PRRSV"). See Appendix G. The vaccines are prepared from attenuated virus, such as ATCC VR-2332, ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), ISU-1894 (VR 2475), or a virus exhibiting identifying characteristics of such viruses. The virus is prepared by serial passage in cell culture in PSP-36, PSP-36-SAH, or MA-104 simian kidney cell lines. The vaccines comprise the attenuated virus and a carrier.

The Primary Proposed Count is set forth in alternative form because of the slightly-different language utilized by the parties to describe the same invention. See Appendices G and L. The primary proposed Count comprises, in the alternative, the subject matter of Claim 55 of the '779 application or Claim 12<sup>2</sup> of the '468 patent.

**"VR 2332" vs. "ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), and ISU-1894 (VR 2475), or a virus exhibiting the identifying characteristics of a virus in said group" vs. "ISU-51 (VR 2429), ISU-55 (VR 2430), ISU-3927 (VR 2431), and ISU-1894 (VR 2475)"**

The presently claimed "low virulence" viruses are highly related to VR 2332 not only in actually chemical structure (*i.e.*, 92-98% sequence identity) by also with respect to the disease and immunological reactions they cause in pigs. See, e.g., U.S. Patent No. 6,773,908; "the '908 patent;" Appendix T.

In particular, the '908 patent discloses:

Sequence comparisons of ORFs 2 to 5 of the seven U.S. PRRSV isolates shown in FIG. 1 indicate that there are considerable nucleotide sequence variations in ORFs 2 to 5 of the U.S. isolates (FIG. 1). The nucleotide sequence identity was 96-98% in ORF 2, 92-98% in ORF 3, 92-99% in ORF 4; and 90-98% in ORF 5 between VR 2385, VR 2332, ISU 22, ISU 55, ISU 79, and ISU 1894 (Table 3). *Appendix T, Col. 26, II. 5-11.*

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<sup>2</sup> While Applicants believe Claim 12 of the '468 Patent best exemplifies the Collins subject matter that interferes with subject matter claimed by Applicants in the present application, Applicants believe that Claim 3 of the '468 Patent would be another exemplary claim from the '468 Patent to use in the Count. See Appendices G and L.

The deduced amino acid sequences of ORFs 2 to 5 of the seven U.S. isolates examined also varied considerably (FIG. 2), indicating that most of the nucleotide differences observed in FIG. 1 are not silent mutations. The amino acid sequence identity between VR 2385, VR 2332, ISU 22, ISU 55, ISU 79, and ISU 1894 was 95-99% in ORF 2, 90-98% in ORF 3, 94-98% in ORF 4, and 88-97% in ORF 5 (Table 3).

*Appendix T, Col. 27, II. 26-33.*

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The phylogenetic tree indicates that at least three groups of variants (or minor genotypes) exist within the major U.S. PRRSV genotype. The least virulent U.S. PRRSV isolate ISU 3927 forms a branch distinct from other U.S. isolates (FIG. 3). Isolates ISU 22, ISU 79, ISU 1894, and VR 2332 form another branch, representing a second minor genotype. The third minor genotype is represented by isolates ISU 79 and VR 2385 (FIG. 3). A very similar tree was also obtained by analyzing the last 60 nucleotides of ORF 1b of the seven U.S. isolates presented in FIG. 1 (data not shown). Identical tree topology was also produced by the unweighted pair-group method with arithmetic mean (UPGMA) using the GeneWorks program (data not shown). *Appendix T, Col. 28, II. 32-44.*

Strain VR 2332 of Collins interferes with the presently claimed low virulence strains of PRRSV, based on *Boehringer Ingelheim Vetmedica Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 65 U.S.P.Q.2d 1961 (Fed. Cir. 2003) ("the BI case" attached as Appendix P). In the BI case, Boehringer argued that "swine infertility and respiratory syndrome virus, ATCC-VR2332" should cover "any PRRS virus." *Boehringer*, 320 F.3d at 1347, 65 U.S.P.Q.2d at 1967. Boehringer also argued that "ATCC-VR2332" should be understood as a "prototype" or "generic" term for all PRRS viruses, rather than as a reference to the deposited strain. *Boehringer*, 320 F.3d at 1348, 65 U.S.P.Q.2d at 1967. As such, Boehringer has admitted that "ATCC-VR2332" should be construed as *all* PRRS viruses, thereby including Applicants' claimed PRRS viruses.

Yet another indication that Applicants' PRRS virus vaccine interferes with Collins' ATCC-VR2332 vaccine comes from Boehringer's patent infringement case against Wyeth's predecessor, American Home Products ("AHP").

On April 15, 1999, Boehringer filed a Complaint and Demand for Jury Trial against AHP alleging infringement of U.S. Patent Nos. 5,476,778; 5,840,563; and 5,846,805. See Appendix AA, Pages 1-2, ¶¶ 108. See also Appendices CC, DD, and EE. Boehringer alleged that AHP's vaccines infringed the '778, '563, and '805 patents. *Id.* at Pages 3-4, ¶¶ 9-16. At that time, a division of AHP, Fort Dodge, marketed a PRRS vaccine under the name Suvaxyn® PRRS. See Appendix BB. Suvaxyn® PRRS utilized ISU-55 as in Applicants' Claims 54-56. See Appendix X. By suing AHP for infringement of the '778 and '805 patents, whose claims are directed to ATCC-VR2332, Boehringer admitted that Applicants' PRRS virus vaccine

and Boehringer's PRRS virus vaccine interfere. Boehringer subsequently dismissed the infringement case against AHP, without prejudice. See *Appendix FF*.

Moreover, the limited number of nucleotide and/or amino substitutions between the presentlyclaimed PRRS viruses and VR 2332 does not render them non-interfering. The Federal Circuit noted in the BI case that "the jury was presented with expert testimony that the two viral genomes are highly similar overall and that any differences between the two are insignificant. A reasonable jury could easily rely on this testimony to conclude that the genetic differences between VR2525 and ATCC-VR2332 are insubstantial." *Boehringer*, 320 F.3d at 1352, 65 U.S.P.Q.2d at 1970.

**B. Proposed Count: Second and Third Alternatives**

Applicants' portion of the second alternative of the Proposed Count, set forth in Appendix B, is very similar to the first alternative of the Proposed Count, but does not contain Applicants' "or a virus exhibiting the identifying characteristics of a virus in said group" language that is found in Applicants' Claim 55, i.e., the first alternative of the Proposed Count.

While Applicants believe that the second alternative of the Proposed Count adequately sets forth interfering subject matter common to the parties, the "or a virus exhibiting the identifying characteristics of a virus in said group" language from the first alternative may be preferred because there can be no doubt that VR 2332 exhibits the identifying characteristics of the members of the presentlyrecited Markush group.

Applicants' portion of the third alternative of the Proposed Count, set forth in Appendix B, is very similar to the first alternative of the Proposed Count, but does

not contain Applicants' "or a virus exhibiting the identifying characteristics of a virus in said group" language that is found in Applicants' Claim 55, *i.e.*, the first alternative of the Proposed Count. In addition, Applicants' third alternative of the Proposed Count states that the vaccine comprises an inactivated or attenuated virus, wherein the virus is a naturally-occurring isolated virus is ISU-51 (VR 2429), ISU-55 (VR 2430), ISU 3927 (VR 2431), or ISU-1894.

**II(b). Identification of Interfering Claims**

Based on Applicants' Proposed Primary Count, Applicants submit that Claim 55 of the present application interferes with Claim 12 of the '468 Patent.<sup>3</sup>

**II(c). Claims Corresponding to the Proposed Counts**

Applicants submit that all claims of the '468 Patent, *i.e.*, Claims 1-19, correspond to the Proposed Count. See Appendix U.

Applicants submit that Claims 54-56 of the present application should be designated as corresponding to the Proposed Count.

**III. Claim Chart Comparing At Least One Claim Of Each Party Corresponding to the Count and Showing Why the Claims Interfere Pursuant to 37 C.F.R. § 41.203(a)**

Please see attached Appendix G.

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<sup>3</sup> Should the Examiner elect to use the Second or Third Alternative of Applicants' Proposed Count, Applicants will update this submission accordingly.

#### IV. Explanation of Why Applicant Will Prevail on Priority

37 C.F.R. § 41.202(d), effective September 13, 2004, requires that a party requesting an interference show why it would prevail on priority. M.P.E.P. § 2304(c) states:

If the application has an earlier constructive reduction-to-practice than the apparent earliest constructive reduction-to-practice of the other application or patent, then the applicant may simply explain its entitlement to its earlier constructive reduction-to-practice. Otherwise, the Applicant must (A) antedate the earliest constructive reduction-to-practice of the other application or patent, **(B) demonstrate why the other application or patent is not entitled to its apparent earliest constructive reduction-to-practice**, or (C) provide some other reason why applicant should be considered the prior inventor. (emphasis added)

Here, Collins claimed priority to, *inter alia*, the earliest three applications from which the '468 patent descended, i.e., U.S. Patent Application Serial No. 07/749,839, filed August 26, 1991, now abandoned; U.S. Patent Application Serial No. 07/760,713, filed September 16, 1991, now abandoned; and U.S. Patent Application Serial No. 07/860,444, filed March 30, 1992, now abandoned. See Appendix K. While Collins undertook the ministerial act of claiming the benefit of the earliest applications, this does not mean that Collins is actually entitled to such benefit. As explained in M.P.E.P. § 201.15 "The only times during *ex parte* prosecution that the examiner considers the merits of an applicant's claim of priority is when a reference is found with an effective date between the date of the foreign filing and the date of

filings in the United States and when an interference situation is under consideration."

See also M.P.E.P. § 201.11.

Applicants believe they will prevail on priority at least because Collins is not entitled to the benefit it claimed for the Collins '468 patent. Specifically, Applicants believe that Collins' priority applications do not enable a vaccine that prevents PRRS.

Applicants base this belief *in part* on proceedings before the European Patent Office. There, European Patent No. 0 830 142 ("the '142 patent"), assigned to Boehringer Ingelheim and sharing three co-inventors with the '468 patent a family member to Collins' '468 patent, was opposed based on the disclosure of European Patent No. 529 584 A2 ("D1").

In a Decision dated March 22, 2005, the European Patent Office announced that the '142 patent could be maintained in amended form. See *Appendix S, Decision, Page 14*. Both the patentee and the opposer have appealed the Decision. In doing so, patentee Boehringer announced, "the virus disclosed in D1 has properties that are unsuitable for a safe vaccine." See *Appendix Y, Boehringer's Grounds for Appeal filed August 1, 2005, Page 7*. Boehringer further asserted that "[t]he inventors of the contested patent surprisingly found that passaging the virus ATCC-VR2332 at least 70 times in the cell line MA-104 results in an attenuated virus which has all desirable properties that render it suitable for use as a master seed virus." *Id. at Page 3*.

Opposer, Wyeth (assignee of the present '779 application), noted in its appeal papers that even when passaged 70 times, Boehringer's vaccine remained unsafe: "earlier this year the Patentee [Boehringer] was fined approximately 3.2 M Euros in

Denmark for the damage result and from spreading of the vaccine virus through the use of the Patentee's vaccine (D12). The Court found that the vaccine did not provide the safety one is entitled to expect and that the vaccine virus was either transmitted in semen or was airborne." See *Appendix Z, Wyeth's Grounds of Appeal filed August 1, 2005, Page 11*. Thus, as late as May 15, 1995, the filing date of U.S. Patent Application No. 440,750, the application to which the '142 patent claims priority, Boehringer did not enable "a vaccine which protects a pig against a porcine reproductive and respiratory syndrome (PRRS)." Applicants, whose vaccine is enabled at least as early as October 5, 1993 (the filing date of the '625 application), should be designated as Senior Party.

#### **V. Written Description For Claims 54-56 of the Present Application**

When a claim has been added or amended to provoke an interference, the requestor is to provide a claim chart showing the written description for each claim in the Applicants' specification. 37 C.F.R. § 41.202(a)(5). Attached Appendix A provides such a claim chart for each of Claims 54, 55, and 56, used in the three alternatives of the Proposed Count.

#### **VI. Disclosure of Constructive Reduction(s) to Practice**

Applicants submit that U.S. Patent Application Serial No. 08/131,625 ("the '625 Application), the grandparent application of the present application, filed October 5, 1993, is a constructive reduction to practice of an embodiment within the scope of each of the three alternatives of the Proposed Count. However, Applicants also maintain that an embodiment within the scope of the Proposed Count was actually reduced to practice prior to October 5, 1993.

Attached Appendix H contains a photocopy of the '625 Application. Attached Appendix I sets forth exemplary support in the '625 Application for Claims 54-56, as set forth in the Proposed Count.

**VII. 35 U.S.C. § 135(b) Is Satisfied**

Under 35 U.S.C. § 135(b), “[a] claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.” 35 U.S.C. § 135(b)(1). As discussed above, the '468 Patent was granted on August 29, 2000. Therefore, August 29, 2001, was Applicants' deadline for satisfying the one-year bar of 35 U.S.C. § 135(b)(1).

As noted above, to comply with 35 U.S.C. § 135(b)(1), one may rely on limitations in more than one claim. See, e.g., *Corbett v. Chisholm*, 568 F.2d 759, 765, 196 U.S.P.Q. 337, 343 (C.C.P.A. 1977); see also *Thompson v. Hamilton*, 152 F.2d 994, 996-97, 68 U.S.P.Q. 161, 163-64 (C.C.P.A. 1946). Applicants had on file, prior to August 29, 2001, claims which together were the same as, or for the same or substantially the same subject matter as, Claim 12<sup>4</sup> of the '468 Patent.

**A. 35 U.S.C. § 135(b)(1) Is Satisfied For The Proposed Count**

The present application was filed on July 15, 2003, as a divisional of U.S. Patent Application Serial No. 08/301,435 (“the '435 application”), filed September 1, 1994, now U.S. Patent No. 6,592,873 (“the '873 patent”), issued July 15, 2003, which was a continuation-in-part of U.S. Patent Application Serial No. 08/131,625 (“the '625

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<sup>4</sup> Applicants maintain that 35 U.S.C. § 135(b)(1) is similarly satisfied for Claim 3 of the '468 Patent.

Application"), filed October 5, 1993, now U.S. Patent No. 5,695,766 ("the '766 patent"), issued December 9, 1997. See Appendix K.

When the '625 Application was filed on October 5, 1993, it contained thirty (30) original Claims. See Appendix H. On February 18, 1994, a Preliminary Amendment was filed that, *inter alia*, amended Claim 22 in several minor/clerical ways. On August 21, 1995, Applicants filed an Amendment that, *inter alia*, canceled Claims 1-9 and 14-30 without prejudice; amended Claim 10; and added new Claims 31-60. See Appendix M. Later, on March 26, 1999, Applicants filed another amendment that, *inter alia*, amended Claims 12 and 32. All of these amendments occurred prior to the '468 patent's 35 U.S.C. § 135 (b)(1) bar date of August 29, 2001.

Claim 55, the first alternative of the Proposed Count, results from a combination of what was Claim 47 in the '625 application (filed with the August 21, 1995, Amendment) and what was Claim 5 in the '625 application (filed with the original application on October 5, 1993) See Appendix C.

Examination of Claims 5 and 47 clearly shows that each feature of the Count, e.g., Claim 12 of the '468 patent, was covered. See *Thompson*, 152 F.2d at 996, 68 U.S.P.Q. at 164. Specifically, at least Claims 5 and 47 intended to secure a property right in vaccines to protect pigs against PRRS using an attenuated PRRS virus produced via serial passage in MA-104 and a carrier - the same subject matter as Claim 12 of the '468 patent. Accordingly, 35 U.S.C. § 135(b)(1) is satisfied for the first alternative of the Proposed Count.

When the present application was filed, Applicants specifically stated "This is a continuation-in-part of application Serial No. 08/131,625, filed on October 5, 1993,

pending, which a continuation-in-part of application Serial No. 07/969,071, filed on October 30, 1992, now abandoned. **The entire contents of application Serial No. 08/131,625, filed on October 5, 1993, are incorporated herein by reference.”** Appendix J, ‘779 Application, Page 1, Lines 7-12 (emphasis added). Should the Examiner wish for Applicants to amend the present Specification to explicitly recite any matter from the ‘625 Application, Applicants will do so upon request.

B. **35 U.S.C. § 135(b)(1) Is Satisfied For The Second Alternative of the Proposed Count**

The present application was filed on July 15, 2003, as a divisional of U.S. Patent Application Serial No. 08/301,435 (“the ‘435 application”), filed September 1, 1994, now U.S. Patent No. 6,592,873 (“the ‘873 patent”), issued July 15, 2003, which was a continuation-in-part of U.S. Patent Application Serial No. 08/131,625 (“the ‘625 Application”), filed October 5, 1993, now U.S. Patent No. 5,695,766 (“the ‘766 patent”), issued December 9, 1997. See *Appendix K*.

When the ‘625 Application was filed on October 5, 1993, it contained thirty (30) original Claims. See *Appendix H*. On February 18, 1994, a Preliminary Amendment was filed that, *inter alia*, amended Claim 22 in several minor/clerical ways. On August 21, 1995, Applicants filed an Amendment that, *inter alia*, canceled Claims 1-9 and 14-30 without prejudice; amended Claim 10; and added new Claims 31-60. See *Appendix M*. Later, on March 26, 1999, Applicants filed another amendment that, *inter alia*, amended Claims 12 and 32. All of these amendments occurred prior to the ‘468 patent’s 35 U.S.C. § 135 (b)(1) bar date of August 29, 2001.

Claim 54, the second alternative of the Proposed Count, results from a combination of what was Claim 47 in the '625 Application (filed with the August 21, 1995, Amendment) and what was Claim 5 in the '625 Application (filed with the original application on October 5, 1993). See *Appendix D*.

Examination of Claims 5 and 47 clearly shows that each feature of the Count, e.g., Claim 12 of the '468 patent, was covered. See *Thompson*, 152 F.2d at 996, 68 U.S.P.Q. at 164. Specifically, at least Claims 5 and 47 intended to secure a property right in vaccines to protect pigs against PRRS using an attenuated PRRS virus produced via serial passage in MA-104 and a carrier - the same subject matter as Claim 12 of the '468 patent. Accordingly, 35 U.S.C. § 135(b)(1) is satisfied for the second alternative of the Proposed Count.

**C. 35 U.S.C. § 135(b)(1) Is Satisfied For The Third Alternative of the Proposed Count**

The '531 Application was filed on May 13, 1997, as a divisional of U.S. Patent Application Serial No. 08/131,625 ("the '625 Application"), filed October 5, 1993, now U.S. Patent No. 5,695,766 ("the '766 patent"), issued December 9, 1997. See *Appendix K*. The '531 Application matured into U.S. Patent No. 6,110,467 ("the '467 Patent") on August 29, 2000. *Id.*

When the '531 Application was filed on May 13, 1997, it contained thirty (30) original Claims. See *Appendix Q, Pages 131-136*. Concurrent with the filing of the application, on May 13, 1997, a Preliminary Amendment was filed in the '531 Application that canceled original Claims 1-30 and added Claims 31-40. See *Appendix N, Pages 1-2*. On April 23, 1998, another Amendment was filed in the '531 Application that, *inter alia*, canceled Claim 32 and amended Claims 31 and 34. See

*Appendix O, Page 23.* All of these amendments occurred prior to the '468 Patent's 35 U.S.C. § 135 (b)(1) bar date of August 29, 2001.

Claim 56, the third alternative of the Proposed Count, results from a combination of what was Claim 34 in the '531 Application (filed with the Preliminary Amendment on May 13, 1997, and amended on April 23, 1998) and what was Claim 5 in the '625 Application (filed with the original application on October 5, 1993). See *Appendix E*.

Examination of Claims 5 and 34 clearly shows that each feature of the Count, e.g., Claim 12 of the '468 patent, was covered. See *Thompson*, 152 F.2d at 996, 68 U.S.P.Q. at 164. Specifically, at least Claims 5 and 34 intended to secure a property right in vaccines to protect pigs against PRRS using an attenuated PRRS virus produced via serial passage in MA-104 and a carrier - the same subject matter as Claim 12 of the '468 patent. Accordingly, 35 U.S.C. § 135(b)(1) is satisfied for the third alternative Proposed Count.

**VIII. CONCLUSION**

From the foregoing, further and favorable consideration in the form of a Declaration of Interference is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this Second Preliminary Amendment Pursuant to 37 C.F.R. § 1.115 and Request for Interference Pursuant to 37 C.F.R. § 41.202, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that declaration of the interference may be expedited.

Respectfully submitted,  
**BINGHAM McCUTCHEN, L.L.P.**

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By: Sharon E. Crane  
**Sharon E. Crane**  
Registration No. 36,113  
**Erin M. Dunston**  
Registration No. 51,147

Three Embarcadero Center  
San Francisco, California 94111-4067  
Local Telephone: (202) 778-6150  
Local Facsimile: (202) 778-6155